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<u>PATENT APPLICATION</u> ATTORNEY DOCKET NO.: 19036/37156

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Yamada et al.) I hereby certify that this paper is being deposited with the United States Postal Service	
Serial No: 09/763,836) as First Class mail, postage prepaid, in an) envelope addressed to: Commissioner for	
Filed: June 8, 2001) Patents, Washington, D.C. 20231 on 2002.	
For: Nucleic Acid Sequences and Methods for Enhancing Expression of Useful Genes		
Group Art Unit: 1636	David A. Gass Registration No: 38,153 Attorney for Applicants	JAN
Examiner: S.S. Pappu, Ph.D.	Attorney for Applicants	7 2 3 7 7 8 7 7 8 7 7 8 7 7 8 7 7 8 7 7 8 7 7 8 7 7 8
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DECLARATION UNDER 37 C.F.R. § 1.132 of DR. JING ZHANG

Commissioner for Patents Washington, D.C. 20231

Sir:

- I, Dr. Jing Zhang, do hereby declare and state as follows:
- 1. I am one of the co-inventors of the subject matter of the above-identified U.S. patent application ("the patent application").
- Zhang, "Hepatitis C Virus Genomic RNA, Complete Sequence," GenBank Accession Number AB016785 having a published submission date of August 5, 1998 (hereafter "the Zhang publication"), cited by the Patent Office in a rejection under 35 U.S.C. § 102(b) of the Office action. To the extent that information reported in the Zhang publication describe or suggest an invention that is claimed in the patent application, the information is the product of experiments performed by me (Dr. Jing Zhang), Dr. Osamu Yamada, and Dr. Hiroshi Yoshida, or people working under our direction. To the extent that the Zhang publication describes or suggests an invention that is claimed in the patent application, the Zhang publication describes or suggest the invention of Dr. Osamu Yamada, Dr. Hiroshi Yoshida, and Dr. Jing Zhang.

3. I further declare that all statements made herein of my own knowledge are true, that all statements made in information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of the application or any patent issuing thereon.

Date November 18, 2002

Dr. Jing Zhang

Atty. Docket No: 19036/37156

DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

As a bel w named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "NUCLEIC ACID SEQUENCES AND METHODS FOR ENHANCING EXPRESSION OF A USEFUL GENE," the specification of which was filed as International Patent Application No. PCT/JP99/03682 on July 7, 1999, was amended under Article 34 during the international phase, was accorded U.S. Patent Application Serial No. 09/763,836 by the United States Patent and Trademark Office, and was amended prior to examination by Preliminary Amendment dated February 27, 2001, a 2nd Preliminary Amendment dated June 8, 2001, a supplement to the 2nd Preliminary Amendment dated December 13, 2001 and Amendment in Response to Office Action dated October 10, 2002. I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

HEI 10-241367 Japan August 27, 1998 ☑ ☐

(Application Serial Number) (Country) (Day/Month/Year Filed) Yes No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

None
(Day/Month/Year Piled)
(Application Serial Number)

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

None
(Application Serial Number) (Day/Month/Year Filed) (Status-Patented, Pending or Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued th reon.

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32 TIX 10 TUE 17:44 FAX 078 391 5791 有古特許事務所 → MARSHALL

27 200 POWER OF ATTORNEY: I hereby appoint as my attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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State or Country Japan Date	Japan Signature Ting 7: hom 9
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APPLICABLE RULES AND STATUTES

CFR 1.56. DUTY OF DISCLOSURE - INFORMATION MATERIAL TO PATENTABILITY (Applicable Portion)

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examinati n occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Offic, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. Ther is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

prior art cited in search reports of a foreign patent office in a counterpart application, and (1)

the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentability defines, to make sure that any material information (2) contained therein is disclosed to the Office.

Information relating to the following factual situations enumerated in 35 USC 102 and 103 may be considered material under CFR 1.56(a).

35 U.S.C. 102. CONDITIONS FOR PATENTABILITY: NOVELTY AND LOSS OF RIGHT TO PATENT

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United

(e) the invention was described in a patent granted on an application for patent by another filed in the United States, or States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraph (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, 10

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. 103. CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER (Applicable Portion)

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of seethen 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same p rson or subject to an obligation of assignment to the same person.

35 U.S.C. 112. SPECIFICATION (Applicable Portion)

The sp cification shall contain a written description f the invention, and of the manner and process f making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connect d, to mak and us the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

APPLICABLE RULES AND STATUTES

37 CFR 1.56. DUTY OF DISCLOSURE - INFORMATION MATERIAL TO PATENTABILITY (Applicable Portion)

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. Ther is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

> prior art cited in search reports of a foreign patent office in a counterpart application, and (1)

the closest information over which individuals associated with the filing or prosecution of a patent (2) application believe any pending claim patentability defines, to make sure that any material information contained therein is disclosed to the Office.

Information relating to the following factual situations enumerated in 35 USC 102 and 103 may be considered material under 37 CFR 1.56(a).

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A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraph (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, 10

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

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Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 192 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, wied by the same person or subject to an obligation of assignment to the same person.

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The sp cification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to mak and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.